Paper No. 17

UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Ex parte SCOTT E. TACKETT

Appeal No. 2001-1925
Application No. 08/677,838

ON BRIEF

Before WINTERS, ADAMS, and GREEN, Administrative Patent Judges.

GREEN, Administrative Patent Judge.

DECISION ON APPEAL

This is a decision on appeal under 35 U.S.C. § 134 from the examiner's final rejection of claim 1, the only claim remaining. Claim 1 reads as follows:

1. A method for reducing wrinkles and discoloration in humans which comprises the step of applying to human tissue skin cells an effective amount of a nuclease solution, said nuclease solution comprised of:

(a) water;

(b) an amount of nuclease equal to from about 1 Kunitz unit per millimeter of water to about 70 Kunitz units per milliliter of water, and

(c) a co-factor capable of activating the nuclease, where after application of said nuclease solution wrinkles are reduced in humans.

The examiner relies upon the following references:

Canadian Patent Application
Tackett 1,312,298 Jan. 5, 1993

Pacifici et al. (Pacifici), "Protein, Lipid and DNA Repair Systems in Oxidative Stress: The Free-Radical Theory of Aging Revisited," Gerontology, Vol. 37, pp. 166-180 (1991)

Claim 1 stand rejected under 35 U.S.C. § 112, first paragraph, on the grounds that specification fails to adequately teach one skilled in the art how to make and/or use the claimed invention. After careful review of the record and consideration of the issue presented, the rejection is reversed.

BACKGROUND

The invention is drawn to the use of known nucleases in solution for the reduction of wrinkles and discoloration in humans. See Specification, page 1. According to the specification:

> [T]he treatment involves altering the gene expression in human skin cells by means of contacting the skin cells with an effective amount of a nuclease solution containing an exogenous nuclease (an enzyme capable of degrading extra-cellular DNA and/or RNA). The nuclease in the nuclease solution will degrade extra-cellular nucleic acids into nucleotides or oligonucleotides which are too short to have substantial avidity for chromosomal DNA. This in turn will prevent oligonucleotides and polynucleotides from binding to the chromosome in human tissue cells, which prevents the over-production of protein and improper production of protein by individual cells. By altering the production of protein, wrinkles are reduced.

Id. at 5.

Four examples are presented. Examples 1, 2 and 4 are drawn to application of the solution to wrinkles, and Example 3 is drawn to the application of the solution to an age spot. Examples 2 and 4 have accompanying pictures, which, according to the specification, demonstrates the reduction in wrinkles. See id. at 16-20. In addition, the specification states in Example 1 that use of the nuclease solution "resulted in the reduction of the subject's wrinkles," id. at 18, and in Example 3, states that "the method results in the reduction of discoloration spots on humans," id. at 19.

DISCUSSION

Claim 1 stands rejected under 35 U.S.C. § 112, first paragraph, on the grounds that the specification fails to adequately teach how to make and/or use the claimed invention, i.e., fails to provide an enabling disclosure.

The rejection focuses on the portions of the specification that explain the purported mechanism of how the nuclease solution may reduce the appearance of wrinkles and age spots. See Examiner's Answer, pages 3-7. However, "it is axiomatic that an inventor need not comprehend the scientific principles on which the practical effectiveness of his invention rests." Fromson v. Advance Offset Plate, Inc., 720 F.2d 1565, 1570, 219 USPQ 1137, 1140 (Fed. Cir. 1983); see also In re Storrs, 245 F.2d 474, 478, 114 USPQ 293, 297 (CCPA 1957) ("It is well established that an applicant for patent need not understand the theory of operation of [his] invention.")

The one relevant portion of the rejection discusses the examples in the specification, and the results as presented by the Figures of the application of the nuclease solution to the skin for the reduction of wrinkles. That portion of the rejection is reproduced below.

> Though the specification provides examples were [sic] the nuclease solution is applied to the skin, the results of these examples (i.e., the photographs) are equivocal. For instance, in Figures 1, 2, and 3, it is not possible to accurately assess the amount of wrinkling present due to the differences in lighting and facial expression. In this example, the specification states that Figure 1 is a photograph of a sixty-four year old female before treatment with the invention, and that Figure 2 is a photograph of the same woman after treatment. However, upon observation, the notable differences in the lighting preclude an accurate assessment of the amount of wrinkling and discoloration. Furthermore, while the photograph in Figure 3 is a clear, close-up profile shot of the same woman after treatment, her facial expression is different (i.e., not smiling which alone reduces folds around the eyes), and moreover, the disclosure fails to provide a corresponding before treatment photograph with which to accurately compare the results. Likewise, Figures 4, 5, and 6 are ambiguous as well. Figures 4 and 4 are the before treatment photographs of a forty-three year old female, yet once again, the lighting combined with the distance are such that no fine details of the skin can be ascertained in Figure 4. Accordingly, that leaves Figure 5 as the only before treatment close-up photograph with which to compare to the after treatment photographs of Figures 6 and 7. Yet, in this photograph (Figure 5) the woman appears to be squinting, something which she is not doing in the other photographs (Figures 6 & 7). Consequently, the absence of the folds present around the eye in Figures 6 and 7 could be the result of her facial expression or the absence thereof (i.e., no squinting). In addition, the pictures do not even address the ability of the claimed method to reduce skin discoloration. Accordingly, the pictures are equivocal and do not support the notion that the claimed method will in fact reduce wrinkles and discoloration in the skin.

Answer, pages 3-4.

The burden is on the examiner to set forth a prima facie case of unpatentability. See In re Glaug, 283 F.3d 1335, 1338, 62 USPQ2d 1151, 1156 (Fed. Cir. 2002). Facts that should be considered in determining whether a specification is enabling, or if it would require an undue amount of experimentation to practice the invention include: (1) the quantity of experimentation necessary to practice the invention, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. See In re Wands, 858 F.2d 731, 737, 8 USPQ2d 1400, 1403 (Fed. Cir. 1988). In order to make a record that is amenable to meaningful review, we recommend that when making an enablement rejection, the examiner should explicitly state the factors as set forth in Wands and set forth facts pertaining to the pertinent factors. See In re Lee, 277 F.3d 1338, 1342, 61 USPQ2d 1430, 1432 (Fed. Cir. 2002) (stating that for meaningful judicial review to occur, the agency must present a full and reasoned explanation of its decision).

The examiner has not set forth a Wands analysis. At most, the examiner's analysis of the pictures is pertinent to the presence of absence of working examples. But in the examiner's own words, the results presented by the pictures are "equivocal" or "ambiguous." The presentation of equivocal or ambiguous results, however, does not in and of itself, support the conclusion that

the specification fails to provide an enabling disclosure. The rejection does not set forth other factors, such as the unpredictability of the art or the level of skill in the art that would support the analysis of the pictures in the rejection, and buttress the conclusion that the specification fails to provide an enabling disclosure.[1] Thus, the examiner has failed to meet the burden of setting forth a prima facie case of enablement, and the rejection is reversed.

OTHER MATTERS

Upon return of the application, the examiner may wish to look at the format of claim 1. Claim 1 specifies that the nuclease solution is comprised of components (a), (b) and (c). There is also a limitation of the claim labeled with (d), which would also make it a component of the nuclease, but the limitation is actually drawn to the step of applying the solution to the skin. Thus, it appears as if the "(d)" should be deleted from the beginning of the application step in order to avoid confusion.

[1] The two references discussed in the rejection as evidence of the unpredictability of the art, i.e., Tackett and Pacifici, are again directed to the putative theory of operation of the invention, and not the treatment of wrinkles and age spots generally.

CONCLUSION

The rejection under 35 U.S.C. § 112, first paragraph, is reversed. In addition, an additional matter has been raised for the examiner's attention upon receipt of the applications.

REVERSED

SHERMAN D. WINTERS Administrative Patent Judge	)
	) BOARD OF PATENT
DONALD E. ADAMS Administrative Patent Judge	) APPEALS AND
	) INTERFERENCES
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